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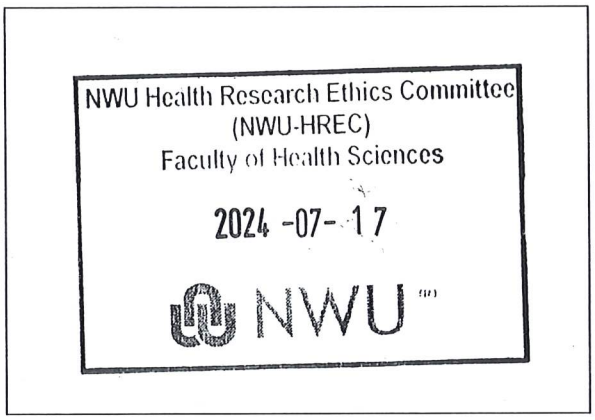

INFORMED CONSENT DOCUMENTATION FOR THE REHAB PROJECT.

TITLE OF THE RESEARCH STUDY: Rehabilitation Enhancement for Human Assessment using Biomechanics (REHAB): A 21st Century Approach to the Appraisal of Musculoskeletal Disorders

ETHICS REFERENCE NUMBERS: NWU-00036-24-A1

PRINCIPAL INVESTIGATOR: Assoc. Prof. Mark Kramer

ADDRESS: Building K3, Human Movement Sciences, Fanie du Toit Sportsgrounds, c/o Thabo Mbeki and Meyer Str, Potchefstroom

CONTACT NUMBER: 018 285 2625

You are hereby invited to participate in this study. The purpose and process of this study will be thoroughly explained. Please read through the information provided and feel free to ask questions if you have any uncertainties. Your participation during this project will be **completely voluntary**, and you may withdraw from the study at any moment or time. Furthermore, you will not be negatively influenced should you withdraw or choose not to take part in this research project.

Before commencement of this project, the research proposal will be submitted to **the Health Research Ethics Committee of the Faculty of Health Sciences of the North-West University** for ethics approval.

What is this research study all about?

There are several objectives of the present study that fall under 4 different sub-headings. Firstly, to mitigate the risk of injury we would like to determine:

- the validity and reliability of a low-cost load cell for evaluating lower extremity isometric strength compared to an isokinetic dynamometer
- the sensitivity and specificity of a low-cost load cell in identifying injured from uninjured limbs
- the validity and reliability of 2D open-source video software for providing kinematic data compared to 3D motion analysis equipment during fixed tasks such as bilateral and unilateral jumping
- the validity and reliability of a cell phone application (e.g., MyJump2) and open-source video software (e.g., OpenCap, Tracker) for providing kinetic and/or kinematic data in clinical settings

Secondly, during post-injury treatment, we would like to determine:

- whether injury-specific questionnaires can be modified (e.g., converted into an application) to allow for more regular insights during rehabilitation in conjunction with objective markers of rehabilitation progress (e.g., use of load cells and force plates to monitor strength, power etc.)

- whether newer technologies such as load cells, force plates, and open-source software increase the clinical decision-making confidence of practitioners during various phases of rehabilitation or performance
- whether newer technologies such as load cells, force plates, and open-source software can provide kinetic and/or kinematic 'thresholds' for specific injuries during the phase-progression decision-making processes

Thirdly, within the context of performance enhancement, we would like to establish:

- whether a computer-based application can monitor and/or enhance exercise adherence and/or compliance
- whether newer technologies such as load cells, force plates, and open-source software are at least as good as, or better than, existing methods for enhancing and/or informing changes related to strength, power, and speed

Finally, during functional re-integration we would like to determine:

- whether new technologies can be incorporated into the clearance decision-making processes
- whether newer technologies may complement or replace existing decision-making criteria for return-to-work or return-to-play decisions
- the ease of use of newer technologies and whether these allow for more regular follow-ups outside of clinical settings (e.g., monitor exercise and rehabilitation adherence and/or compliance).

Why have you been invited to participate?

The following criteria will need to be met for you to take part in this study:

Inclusion criterion	**Justification**
Aged 18-60	Participants would need to be self-sufficient (i.e. be able to drive to and from testing venues, make individual decisions etc) to partake in the study. Therefore, those younger than 18 would be ineligible. Furthermore, to account for maturational influences, which are more prevalent in children and younger adolescents, this group will not be included. The

	equipment used in this study is additionally adult sized. Physiological, mechanical, and energetic changes are more inherent in those above the age of 60 and would potentially serve as a confounding variable.
Not exhibit any cardiovascular disease	Those with cardiovascular disease typically have comorbidities as well as medications that in combination would serve as confounders for the study.
Reside within the Tlokwe District and Mafikeng area	The study is reliant on the ability of participants to visit the specicialised testing facilities. To minimise any stress/risk associated with extensive travel, only those within the Tlokwe district would be eligible. In the Mafikeng area, participants will take part in testing activities at the North-West University Human Movement Science division.
Must exhibit one or more MSDs	The project focuses of the use of various technologies in identifying those with an MSD, therefore this is a crucial component which will be identified during the eligibility screening process. Eligible MSD for this study include: lower extremity muscle/tendon strain and/or ligament sprain, or back pain.

If you are part of the control group, then the last part of the inclusion criteria will not apply to you since you would need to be free of any injury.

If you are a practitioner, then the following inclusion criteria will apply:

Inclusion criterion	**Justification**
Skilled professionals (e.g., physiotherapists, biokineticists, sport scientists, sports coaches) with at least 2 years working experience who render (or who are part of) key rehabilitation and performance-related services to a client for at least one of the phases of the	Since interviews will be conducted, the skilled professionals (e.g., physiotherapists, biokineticists, sport scientists, sports coaches) must have been involved in the rehabilitation and performance-related services for at least *one* of the adherence and compliance aspects of the programme to be assessed. Two years is a reasonable lower limit for clinical experience since, on the one hand, it would be sufficient to gain excellent clinical insights, and on

rehabilitative or performance-related services.	the other hand, would provide room to evaluate the uncertainties inherent in the decision-making processes that are of interest in the present study.

You will not be able to take part in this study for the following reason:

Exclusion criterion	**Justification**
Presence of any cognitive impairments	The ability to understand any and all instructions, as well as adhere to the various testing protocols would be crucial. Therefore, any cognitive impairments that would hinder the above-mentioned factors would preclude participation in the study.
Not exhibit any cardiovascular disease (or associated comorbidities e.g., diabetes, obesity)	Those with cardiovascular disease typically have comorbidities (e.g., diabetes, obesity) as well as medications that in combination would serve as confounders for the study.
Pregnancy	Pregnancy would serve as a contraindication as various physiological, mechanical, and energetic profiles change over time.

If you are a practitioner, then the following exclusion criteria will be applied:

Exclusion criterion	**Justification**
Skilled professionals (e.g., physiotherapists, biokineticists, sport scientists, sports coaches) who cannot provide proof of their qualifications and/or registrations with the HPCSA.	The individuals who are part of the rehabilitation and performance-related services should have some qualifications to render the services they provide. The qualifications provided should guarantee that the person can do the job they have been allocated to do.
Skilled professionals (e.g., physiotherapists, biokineticists, sport scientists, sports coaches) who render (or who are part of) key rehabilitation and performance-related services to a client for less than one month, unless the client decided to leave out of their own accord.	It is important /for the skilled professional to have experienced the rehabilitation and performance related data presented within this research. Depending on the MSD, a time period of at least 4 weeks should be engaged in by the client to ensure for some physiological adaptations to the MSD intervention. This minimum time period accounts for the varying exercise prescriptions (duration, frequency per week etc.), age, gender, physiological

	adaptation, and other possible mitigating factors affecting rehabilitation.

What will be expected of you?

Please take note of the following responsibilities:

- Prior to testing you will need to complete and sign the informed consent.
- Complete the following questionnaires:
    - Cardiovascular Disease (CVD) risk questionnaire
    - Physical Activity Readiness Questionnaire (PAR-Q)
    - International Physical Activity Questionnaire (IPAQ)
    - Nordic Musculoskeletal Questionnaire (NMQ)
    - Musculoskeletal Health Questionnaire (MSK-HQ) and
    - Regular training log
- Body stature and weight will be measured along with performance testing to evaluate lower body strength, explosive power, and stability. In general, the following tests would be completed:
    - Isokinetic dynamometry
    - Isometric contraction using a load-cell
    - Jumping tests (countermovement jump, squat jump, drop jump, and repeated jumps)
- Prior to transition to the next phase of rehabilitation all these tests will be repeated (i.e., every 6-12 weeks) until you are completely cleared and/or free from injury.
- It will be expected of you to give 100% effort for each test to ensure accurate results.

Will you gain anything from taking part in this research?

Yes, the direct benefits associated with taking part in this study are:

- You will receive a report and learn about your own muscle strength discrepancies and imbalances and how to correct these
- You will receive a report about your dynamic strength, power, and balance abilities and how these change across time
- You will receive objective measures about your readiness to progress to subsequent phases of training

Indirect benefits will include:

- Reassurance about your current condition and how this changes over time
- Learn about limb strength deficits and asymmetries that might be present and how to correct for this

Are there risks involved in you taking part in this research and what will be done to prevent them?

Yes, there are potentially some risks associated with testing, although these will be minimised:

- You may experience muscle fatigue during training sessions and testing
- You may experience some delayed onset of muscle soreness (DOMS) associated with isometric strength testing and with jump testing. Symptoms usually last for 2-3 days after which these symptoms tend to subside. To mitigate the risk of developing DOMS you will complete a comprehensive warm-up protocol prior to each testing session which will be guided by a qualified biokineticist or sports scientist
- There is a marginal risk of losing balance during jump testing. Mats will be present that would cushion any potential fall
- It is important to note that the benefits far outweigh the risks associated with taking part in the present study

How will we protect your confidentiality and who will see your findings?

- The anonymity of participants will be ensured in that only the principal investigator has access to the questionnaires and data sheets. No form of identity of the participants will appear in the published articles upon completion of the study. Each participant will be allocated a reference number, which will blind the identity of the participant to the researcher and any potential graduate assistants collecting the data.
- The clinicians involved in the study will receive a report pertaining to the results, whereas participants will receive individual reports within two weeks after the data collection reflecting the findings and recommendations. These reports will be emailed individually and will enable participants to evaluate their performance. Participants will be afforded an opportunity to talk to the researchers about their results which may be done in-person or electronically (email, Zoom etc).

What will happen with the findings or samples?

- The anonymised data from this study may be used in the completion of a Master's or Doctoral degree and various scientific publications.
- All hard copies of the data, including the completed questionnaires, will be scanned electronically and kept safe and secure by storing electronic copies of the data on a desktop computer and a password-protected external hard drive in the study/project leader's office at the North-West University (NWU), Potchefstroom Campus, for a period of 7 years where-after it will be destroyed. Furthermore, the data will be backed up on RedCap, a cloud-based system, at the North-West University.

How will you know about the results of this research?

- The results will be given to you within approximately 2 weeks after the final data has been captured and processed in the form of individual reports via email.
- You will have the option to talk to the researchers of this study about your results via zoom or in-person.
- You will be informed of any new relevant findings via email.

Will you be paid to take part in this study and are there any costs for you?

- You will not be paid to take part in the study because this will form part of your normal training schedule.
- There will thus be no costs involved for you if you do take part in this study.

Is there anything else that you should know or do?

- You can contact Dr Mark Kramer at mark.kramer@nwu.ac.za if you have any further questions or uncertainties.
- You can also contact the NWU-Health Research Ethics Committee via Mrs Carolien van Zyl at 018 299 1206 or carolien.vanzyl@nwu.ac.za if you have any concerns that were not answered about the research or if you have complaints about the research.
- You will receive a copy of this information and consent form for your own purposes.

Do you consent to your data being used in future for longitudinal follow-up research? Note: Please note that none of your personal information will be retained, all of your data will be anonymised, and therefore your confidentiality will be adhered to at all times.

(please tick)

Yes	**No**

Declaration by participant

By signing below, I ..... agree to take part in the research study titled: Rehabilitation Enhancement for Human Assessment using Biomechanics (REHAB): A 21st Century Approach to the Appraisal of Musculoskeletal Disorders

I declare that:

- I have read this information/it was explained to me by a trusted person in a language with which I am fluent and comfortable.
- The research was clearly explained to me.
- I have had a chance to ask questions to both the person getting the consent from me, as well as the researcher and all my questions have been answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be handled in a negative way if I do so.
- I may be asked to leave the study before it has finished, if the researcher feels it is in the best interest, or if I do not follow the study plan, as agreed to.

Signed at (*place*) ..... on (*date*) ..... 20....

Signature of participant **Signature of witness**

Declaration by person obtaining consent

I *(name)* ..... declare that:

- I clearly and in detail explained the information in this document to

.....

- I did/did not use an interpreter.
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I gave him/her time to discuss it with others if he/she wished to do so.

Signed at (*place*) ..... on (*date*) ..... 20....

Email Address: .....

Signature of person obtaining consent

Declaration by researcher

I *(name)* ..... declare that:

- I explained the information in this document to ..... **or** I had it explained by ..... who I trained for this purpose.
- I did not use an interpreter.
- I encouraged him to ask questions and took adequate time to answer them

  or I was available should he want to ask any further questions regarding this study.
- The informed consent was obtained by an independent person.
- I am satisfied that he/she adequately understands all aspects of the research, as described above.
- I am satisfied that he/she had time to discuss it with others if he/she wished to do so.

Signed at (*place*) ..... on (*date*) ..... 20....

Signature of researcher